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PATENT
Customer No. 22,852
Attorney Docket No. **6530.0020-02**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

#25/Brief

In re Application of:	
Brett Haarala et al.	Group Art Unit: 3763
Application No.: 09/690,473	Examiner: M. Hayes
Filed: October 18, 2000	
For: GUIDEWIRE COMPATIBLE PORT AND METHOD FOR INSERTING SAME	

Mail Stop Appeal Brief- Patents

Commissioner for Patents and Trademarks
Washington, DC 20231

Sir:

APPEAL BRIEF UNDER 37 C.F.R. § 1.192

Pursuant to 37 C.F.R. § 1.192, Appellants submit this Appeal Brief, in triplicate, to the Board of Patent Appeals and Interferences, from the March 19, 2003, final Office Action in which the Examiner rejected all of the pending claims. A Notice of Appeal was filed on July 15, 2003, along with a Petition for Extension of Time. This Appeal Brief is timely filed along with a Petition for Extension of Time and payment of the fees associated with the filing of the Appeal Brief and the extension of time.

I. Real Party In Interest

The real party in interest is Boston Scientific Corporation, the assignee of the entire right, title, and interest in the application.

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II. Related Appeals and Interferences

There are currently no related appeals or interferences pending before the Board of Patent Appeals and Interferences.

III. Status Of Claims

Claims 60, 61, 63-68, 70-72, 74-79, 113, and 114 are pending. Each of those claims was rejected in the final Office Action. All of the rejected claims are involved in this appeal and set forth in the attached Appendix.

IV. Status Of Amendments

An Amendment After Final was filed on June 17, 2003. In an Advisory Action dated July 1, 2003, the Examiner indicated that the Amendment After Final would be entered for purposes of Appeal. Accordingly, Appellants understand the Amendment After Final was entered, leaving claims 60, 61, 63-68, 70-72, 74-79, 113, and 114 as the pending claims.

V. Summary Of Invention

The present invention generally relates to an access port device to be implanted in a patient's body. Such a device may be used to enable a fluid to be introduced into and/or removed from a remote area in a patient by passing a needle, specially designed cannula, or other structure through a self-sealing septum associated with the access port. Such an implantable arrangement may be particularly useful when a patient requires frequent insertion and/or removal of fluids.

The exemplary embodiment of Figs. 7-9 includes an upper body part 42, a lower body part 50, and a self-sealing septum 52 therebetween. Page 9, lines 15-16. The body parts 42 and 50 are formed of implantable, biocompatible material. See, e.g., page 10, lines 2-3. The upper body part 42 defines a hole 46 (an exemplary entry site)

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for inserting a guidewire or stylet into the device (via the septum 52) and into a catheter 12 attached to the device. Page 9, lines 12-15, page 9, line 19- page 10, line 2, and Figs. 7 and 8. The upper body part 42 also includes an open target area 44 (an exemplary access site) through which the septum 52 is exposed so that a needle, cannula or other apparatus may be passed into the device via the septum, wherein an outer surface of the septum forms a portion of an exterior surface of the device. Page 9, line 12-18.

Claims 60 and 70 are the sole independent claims involved in this appeal. As discussed in more detail below, each of those independent claims positively recites, *inter alia*, a self-sealing septum between upper and lower body parts, wherein the upper and lower body parts are formed of implantable, biocompatible material, and wherein an outer surface of the septum forms an outer surface of the device. Claim 60 recites an entry site disposed opposite an outlet of the device and configured to permit insertion of one of a guidewire or a stylet. Claim 70 recites both an access site and an entry site.

VI. Issues

A. Whether the rejection of claims 60, 61, 63-68, 70-72, and 74-79 under 35 U.S.C. § 102(b) based on U.S. Patent No. 4,840,615 to Hancock et al. ("Hancock") should be reversed.

B. Whether the rejection of claims 60, 61, 63-68, 70-72, and 74-79 under 35 U.S.C. § 102(b) based on U.S. Patent No. 4,857,053 to Dalton ("Dalton") should be reversed.

C. Whether the rejection of claims 60, 61, 63-65, and 68 under 35 U.S.C. § 103(a) based on U.S. Patent No. 4,000,740 to Mittleman ("Mittleman") in view of U.S. Patent No. 5,718,682 to Tucker ("Tucker") should be reversed.

D. Whether the rejection of claims 113 and 114 under 35 U.S.C. § 103(a) based on Hancock, Dalton, U.S. Patent No. 5,108,377 to Cone et al. ("Cone"),

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Mittleman, and/or Tucker and further in view of U.S. Patent No. 5,403,283 to Luther ("Luther") should be reversed.

E. Whether the rejection of claims 113 and 114 under 35 U.S.C. § 103(a) based on Hancock, Dalton, Cone, Mittleman, and/or Tucker and further in view of U.S. Patent No. 5,556,381 to Ensminger et al ("Ensminger") should be reversed.

VII. Grouping Of Claims

All of the rejected claims do not stand or fall together.

Regarding each of the Section 102(b) rejections, claims 60, 61, 63-68, 70-72, and 74-79 stand or fall together.

Regarding the Section 103(a) rejection based on Mittleman and Tucker, claims 60, 61, 63, and 64 stand or fall together, and each of claims 65 and 68 stands or falls on it own.

Regarding each of the Section 103(a) rejections of claims 113 and 114, each of claims 113 and 114 stands or falls on its own.

VIII. Argument

A. The Section 102(b) Rejection Based on Hancock Should Be Reversed Because There is No Teaching of a Septum Between Upper and Lower Body Parts Wherein the Septum Forms an Exterior Surface Portion of an Access Port Device

Appellants respectfully submit that the Section 102(b) rejection based on Hancock should be reversed because that reference does not disclose all of the subject matter of independent claims 60 and 70. For example, that reference lacks any disclosure of an access port device including, among other elements, a septum between upper and lower body parts, "wherein an outer surface of the septum forms a portion of an exterior surface of the device," as recited in claims 60 and 70.

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Hancock discloses a self-sealing injection reservoir adapted to be implanted. In the final Office Action, the Examiner has apparently alleged that a sealing plate 28 shown in Figs. 2-5 of Hancock corresponds to the septum recited in claims 60 and 70. The Examiner has cited Hancock at col. 5, lines 16-20 for the asserted disclosure of a "septum outer surface [that] is exposed exteriorly." Contrary to the Examiner's apparent assertion, however, that cited portion of Hancock merely mentions that the sealing plate 28 shown in Figs. 2-5 is preferably made from biocompatible silicone rubber, but that "it does not need to be biocompatible unless it is exposed for contact with living tissue (not shown)." Hancock does not include any explicit disclosure or suggestion of any part of the plate 28 forming a portion of an exterior surface, and Hancock even acknowledges that exposing the sealing plate 28 for contact with living tissue is "not shown." Furthermore, it is not clear how the arrangement briefly discussed at col. 5, lines 16-20 would be configured because the drawings of Hancock show a top portion 26 completely covering the sealing plate 28 so that no part of the sealing plate 28 contacts living tissue or defines an exterior surface. Moreover, Hancock contains no disclosure whatsoever of an injection reservoir that lacks an exterior casing, like top portion 26, and a base, like base 24, that surround the sealing plate.

Since Hancock lacks any explicit disclosure of the subject matter of claims 60 and 70, Appellants assume that the Examiner is relying on an allegation of inherency in the claim rejection.[1] Assuming the claim rejection does rely at least in part on an inherency position, the rejection is flawed even further because the Examiner has failed

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[1] If the Examiner is taking an inherency position, Appellants request that the Examiner clarify the record in the Examiner's Answer by providing a written indication of whether or not the claim rejection relies on inherency.

to satisfy the requirements for a proper inherency-based rejection, as dictated by legal precedent:

> To establish inherency, the extrinsic evidence "must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill." "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient."

In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)(citations omitted).

Clearly, the Examiner has not satisfied the burden of establishing inherency merely by presenting his unsupported allegations about his interpretation of Hancock at col. 5, lines 16-20. Appellants submit that Hancock's mere mention of the possibility of the plate 28 being made of biocompatible material in the event it might possibly be exposed to contact living tissue does not provide inherent disclosure of the plate 28 having an outer surface forming a portion of an exterior surface of Hancock's injection reservoir. In other words, contrary to the Examiner's assessment at page 5 of the final Office Action, merely because Hancock discloses that the sealing plate 28 does not need to be formed of biocompatible material unless it is exposed to contact living tissue does not require the sealing plate 28 to form an exterior surface.

There could be numerous arrangements that might expose Hancock's plate 28 to contact living tissue without plate 28 necessarily having an outer surface forming an exterior surface portion of the injection reservoir. For example, the exposure to tissue contact that is mentioned in Hancock might possibly refer to an arrangement in which the sealing plate 28 is completely enclosed by the top portion 26 and the base 24 (i.e.,

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the top portion 26 and base 24 define the entire exterior surface), as shown in Figs. 2-5, but the sealing plate 28 is formed of biocompatible material so that if a flap or some other structural passage forms in the outer layer 26 during use, movement of such a flap or other formation of a passage would temporarily place biocompatible material of the plate 28 in contact with living tissue. Such disclosure in Hancock might also relate to a configuration where the sealing plate is formed of biocompatible material (despite not defining any part of the exterior surface) merely to provide an additional degree of safety in the event Hancock's injection reservoir breaks apart in an unintended manner within a patient due to an unforeseen circumstance (e.g., a defect). Accordingly, Hancock at col. 5, lines 16-20 does not disclose, either explicitly or inherently, "an outer surface of the septum [that] forms a portion of an exterior surface of the device," as recited in claims 60 and 70.

For at least these reasons, the Examiner's improper Section 102 rejection of claims 60 and 70 based on Hancock should be reversed. And since claims 61, 63-68, and claims 71, 72, and 74-79 depend respectively from those independent claims, the Section 102 rejection of those claims should be reversed for at least the same reasons.

B. The Section 102(b) Rejection Based on Dalton Should Be Reversed in Light of a Lack of Disclosure of a Septum Between Upper and Lower Body Parts Wherein the Septum Forms an Exterior Surface Portion of an Access Port Device

Dalton also lacks disclosure or suggestion of an access port device including, among other elements, a septum between upper and lower body parts, "wherein an outer surface of the septum forms a portion of an exterior surface of the device," as recited in claims 60 and 70.

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Dalton discloses a drug delivery device including a matrix septum material for containers, especially those in the medical field, such as implanted drug delivery devices. Col. 1, lines 1-10. As shown in Figs. 1-3 of the reference, a matrix septum material 20 consists of a resilient, elastomeric, needle penetrable layer 25, webs 30 and 31 contacting opposite faces 26 and 27 of the layer 25, respectively, and means 50 urging the webs 30 and 31 together. Col. 3, lines 36-42. The webs 30 and 31 are disclosed as being formed of loosely woven material, metal wire screen, wire, or a perforated metal or plastic sheet. See, generally, col. 4, line 24 through col. 5, line 27. Figs. 4 and 5 of Dalton illustrate an implantable drug delivery device including the matrix septum 20, and Fig. 6 illustrates a method of making the device of Figs. 4 and 5. Col. 3, lines 28-35 and col. 6, lines 20-21 and 34-37. Rather than having the matrix septum 20 form any portion of the exterior surface of drug delivery device, Dalton discloses a silicone layer 66 coating the matrix septum 20. Col. 6, lines 28-29. Consistent with that disclosure of coating the matrix septum so that none of the matrix septum forms an exterior surface of the drug delivery device, Dalton discloses first and second examples where an entire port is potted in (i.e., covered with) a layer of silicone rubber. Col. 6, lines 65-66 and col. 7. lines 16-17. Dalton also discloses a third example having a silicone gel sandwiched between elastomer sheets, but Dalton's brief description of that example renders it somewhat unclear as to whether one of the elastomer sheets and/or a septum forms an exterior surface. Col. 7, lines 27-41.

The final Office Action lacks any clear indication of how the Examiner is applying Dalton in the Section 102(b) rejection. Appellants believe the Examiner might be

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alleging that that web 30 of Dalton corresponds to the recited upper body part,[2] and that Dalton's elastomeric layer 25 corresponds to the recited septum. Such an apparent allegation is insufficient to support the claim rejection because no surface of the elastomeric layer 25 forms any part of the exterior surface of Dalton's drug delivery device.

In the paragraph bridging pages 5 and 6 of the final Office Action, the Examiner has alleged that Dalton discloses an "embodiment without the [outer] covering [66], [where] the septum's outer surface forms an exterior surface (col. 5, line 66 - col. 6, line 48)." Contrary to the Examiner's allegation, however, there does not appear to be any such disclosure in Dalton. As discussed above, Dalton discloses a drug delivery port embodiment and examples having either an outer layer coating 66 (col. 6, lines 28-29, and Figs. 4-6) or an outer potting layer (col. 6, lines 65-66, and col. 7, lines 16-17) completely covering the matrix septum so that no part of the matrix septum forms any part of the exterior surface of the drug delivery port. The portion of Dalton cited by the Examiner (col. 5, line 66 - col. 6, line 48) simply does not disclose any alleged drug delivery port "embodiment without the [outer] covering [66]," as alleged by the Examiner.

For at least these reasons, the Section 102(b) rejection of independent claims 60 and 70 and dependent claims 61, 63-68, 71, 72, and 74-79 based on Dalton should be reversed.

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[2] Appellants do not understand the Examiner's apparent allegation concerning the alleged disclosure of an upper body part. For example, the web 30 is disclosed as being part of Dalton's matrix septum 20, and therefore the web 30 defines a part of a septum rather than defining an upper body part. Furthermore, one of ordinary skill in the art would not consider the web 30 shown in the drawings of Dalton as corresponding to an upper body part.

C. The Section 103(a) Rejection Based on Mittleman in View of Tucker Should Be Reversed Because the Final Office Action Fails to Set Forth a *Prima Facie* Case of Obviousness

Appellants respectfully submit that the 35 U.S.C. § 103(a) rejection of claims 60, 61, 63-65, and 68 should be reversed because the Examiner has not established a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness under 35 U.S.C. § 103, three basic criteria must be satisfied. First, "there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify a reference or to combine reference teachings." M.P.E.P. § 2143. "Second, there must be a reasonable expectation of success." Id. Third, "the prior art reference (or references when combined) must teach or suggest all the claim limitations." Id. Moreover, "[t]he teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure." Id. (citing In re Vaeck, 947 U.S.P.Q.2d (BNA) 1438 (Fed. Cir. 1991)).

The final Office Action fails to set forth a *prima facie* case of obviousness inasmuch as Mittleman and Tucker do not suggest an access port device to be implanted in a patient's body, including, among other elements, an upper body part and a lower body part "formed of implantable, biocompatible material," as recited in claim 60.

Mittleman discloses an injection site 10 having a main body portion 12, first and second inlets 14, 16, and a diaphragm 26. Col. 3, lines 13-21 and Fig. 1. As discussed in the Background of the Invention section of Mittleman, the injection site disclosed in that reference is a device commonly used in a hospital setting when it is desired to

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combine a medicament with a parenteral fluid (e.g., I.V. fluid) being fed to a patient intravenously. Col. 1, lines 7-11. Such injection sites are always positioned along tubing placed between the parenteral fluid source and the delivery device (e.g., needle) inserted in the patient without ever being implanted in the patient. Accordingly, one of ordinary skill in the art would not consider Mittleman as disclosing an "access port device to be implanted in a patient's body," as recited in claim 1.

In contrast, as described, in the Background of Invention section of the present application, for example, the term "access port" has an art-recognized meaning. In general, an "access port" is a device that is **implanted** into a patient. When the access port is implanted into the patient, for example, a needle, specially designed cannula, or other device can be passed through a self-sealing septum associated with the access port so that fluids can be easily introduced into and/or removed from a remote site in a patient. Such an implantable arrangement is particularly useful when a patient requires frequent insertion and/or removal of fluids.

Although the Examiner is permitted to give claims their broadest reasonable interpretation, M.P.E.P. § 2111 requires that such an interpretation must be "**consistent with the specification**" (emphasis supplied). Further, that section of the M.P.E.P. specifies that "[t]he broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach." Id. (citing In re Cortright, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999)). After considering the specification, one skilled in the art would construe the recited "access port device" as being a device that is configured to be implanted into a patient's body. With such an art-recognized interpretation of the access port device, one of ordinary

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skill in the art would consider that the injection site 10 disclosed in Mittleman is not an access port device.

Moreover, since Mittleman discloses an injection site that would never be implanted, that reference does not disclose or suggest "implantable, biocompatible material," as recited in claim 60.

Based on the Examiner's statements in the final Office Action at the paragraph bridging pages 6 and 7, Appellants are uncertain of whether the Examiner is alleging that Mittleman inherently discloses "implantable, biocompatible material." If the Examiner is making such an inherency allegation, Appellants submit that the claim rejection is flawed even further because such material is not "necessarily present" in the subject matter disclosed in Mittleman. In re Robertson, 169 F.3d at 745. Appellants acknowledge that Mittleman generally discloses forming inlets 14 and 16 and body portion 12 of non-pierceable plastic material (col. 3, lines 28-29 and 34-35) and that the reference also discloses the injection site being taped to a body (col. 4, lines 3-4). Such disclosure, however, does not provide any teaching or suggestion that Mittleman's injection site is necessarily formed of implantable, biocompatible material. One of ordinary skill in the art would readily recognize that there are several suitable "non-pierceable plastic material[s]" that would not necessarily be implantable, biocompatible materials, and the Examiner has not satisfied his burden of establishing otherwise.

Contrary to the Examiner's apparent allegation, the mere fact that Mittleman discloses an injection site used to administer fluid intravenously does not provide any indication that the injection site is inherently formed of "implantable, biocompatible material." Since there is no disclosure or suggestion of implanting Mittleman's injection

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site in a patient, it follows that the reference does not "necessarily" disclose an injection site formed of "implantable, biocompatible material." Accordingly, Mittleman lacks any express or inherent teaching of an access port device to be implanted in a patient's body, wherein the access port device includes an upper body part and a lower body part "formed of implantable, biocompatible material."

Due to there being a lack of a clear explanation of the claim rejection, Appellants believe it might be possible that the Examiner is relying on some form of an allegation of obviousness for the above-noted deficiencies of Mittleman. If so, Appellants submit that the claim rejection is still improper because there would have been no suggestion or motivation for one of ordinary skill in the art to have modified the injection site of Mittleman in the form of an access port device to be implanted in a patient's body and further to form such an injection site from implantable, biocompatible material.

The Examiner asserts, at page 4 of the final Office Action, that it would be obvious to modify Mittleman with titanium material disclosed in Tucker "to provide a device compatible with bioactive fluids." This reasoning is clearly based on hindsight gleaned from the present application. As mentioned above, the injection site of Mittleman would not be implanted within the body of a patient and, as such, there would be no plausible reason why one of ordinary skill in the art would look to Tucker for any asserted teaching of implantable, biocompatible material. Tucker provides no teaching or suggestion to modify the material of a non-implanted, parenteral injection site such as that taught by Mittleman. Moreover, one of ordinary skill in the art would not chose titanium to form the injection site of Mittleman because such a material is rather expensive and difficult to form into a given shape, especially compared to many suitable

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plastic materials that would be non-pierceable plastic materials capable of being used to form an injection site that might be taped to a body. Therefore, there is no suggestion of the subject matter recited in claim 60 and there would have been no motivation to combine the references as proposed by the Examiner.

For at least these reasons, the Section 103(a) rejection applied to independent claim 60 and dependent claims 61, 63-65, and 68 should be reversed.

Regarding each of claims 65 and 68, the Section 103(a) rejection should also be reversed because Mittleman lacks any disclosure or suggestion of the claimed subject matter (i.e., an outlet extending in a first direction and an access site extending in a second direction substantially perpendicular to the first direction (claim 65), and a catheter connected to the outlet (claim 68)), and because there is no suggestion or motivation for modifying Mittleman to include such subject matter. Consequently, there are additional reasons for reversing the Section 103(a) rejection for each of claims 65 and 68.

D. The Section 103(a) Rejection of Claims 113 and 114 Based on Hancock, Dalton, Cone, Mittleman, and/or Tucker and further in view of Luther Should Be Reversed Because There is No *Prima Facie* Case of Obviousness

Appellants submit that the 35 U.S.C. § 103(a) rejection of claims 113 and 114 based on the asserted combination of references including Luther should be reversed because the Examiner has not established a *prima facie* case of obviousness.

As an initial matter, Appellants note that despite the request set forth in the Amendment filed on January 2, 2003, at page 18, the Examiner has failed to set forth any meaningful explanation of the Section 103(a) rejections applied to claims 113 and 114. Accordingly, Appellants do not understand how the Examiner is applying the cited

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references in the those claim rejections. For example, the final Office Action does not explain the extent to which (or even how) the rejections applied to claims 113 and 114 rely on Cone, Mittleman, and Tucker. Inasmuch as the final Office Action does not set forth any clear indication of the rejection of claims 113 and 114, the Examiner has not set forth a *prima facie* case of obviousness.

Claims 113 and 114 depend from claims 60 and 70, respectively. Claims 60 and 70 are allowable over Hancock, Dalton, Mittleman, and Tucker for all of the reasons discussed in the above remarks addressing the Section 102(b) and 103 rejections of claims 60 and 70. Since Luther is not being relied upon to supply any the above-noted deficiencies of those references, the Section 103(a) rejection of claims 113 and 114 should be reversed at least to the extent it relies on Hancock, Dalton, Mittleman, Tucker, and Luther.

Regarding Tucker, there is no disclosure or suggestion of either an entry site "disposed opposite" an outlet, as recited in claim 60, and there is also no disclosure or suggestion of both an entry site and an access site as recited in claim 70.[3] Luther does not supply these deficiencies and it does not appear to be relied upon for such. Therefore, if the rejection relies on some form of a combination of Tucker and Luther, it should be reversed.

Furthermore, there is no suggestion or motivation to combine any of the cited references with Luther, and, for at least some of the references, even if such a combination could be made, the claimed invention would not result. For example, there

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[3] Appellants note the Examiner's comments in the Office Action at page 6 concerning Tucker's alleged disclosure of an entry site and access site positioned opposite from an outlet. Since the final Office Action does not adequately explain how Tucker allegedly discloses such subject matter, Appellants are unable to understand the Examiner's allegations.

is no motivation or suggestion to combine Mittleman's injection site with the stylet of Luther because there would not have been any reason to associate a stylet with a non-implanted injection site. To show another example, there would have been no motivation or suggestion to combine Cone and Luther and, even if they could be combined, any combination would not result in a configuration permitting insertion of a guidewire or stylet through a body portion and into an outlet, as recited in claims 113 and 114, because Cone requires an outlet connector 38 and bore 40 defining a filter system that would prevent passage of a stylet into bore 40. Furthermore, since Luther merely discloses an arrangement including a stylet that is used to pass a catheter into a port, apparently without having any disclosure of a stylet that would pass through a body and into an outlet, any attempted combination of Luther and the other references would not result in the claimed subject matter of claims 113 and 114.

For at least these reasons, Appellants submit that the Section 103 rejection of claims 113 and 114 should be reversed.

E. The Section 103(a) Rejection of Claims 113 and 114 Based on Hancock, Dalton, Cone, Mittleman, and/or Tucker and Further in View of Ensminger Should Be Reversed Because There is No *Prima Facie* Case of Obviousness

Appellants submit that the 35 U.S.C. § 103(a) rejection of claims 113 and 114 based on the asserted combination of references including Ensminger should be reversed because the Examiner has not established a *prima facie* case of obviousness. In particular, the rejection should be reversed for reasons substantially the same as those discussed above in connection with the Section 103 claim rejection based on Luther (i.e., all of the comments in section VIII, E. concerning Hancock, Dalton, Cone Mittleman, and Tucker apply in the same manner to the rejection citing Ensminger). In

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addition, the rejection should be reversed because Ensminger teaches away from any combination of its teachings with references such as Hancock, Dalton, Cone, and/or Tucker. That is, Ensminger teaches away from implantable port configurations, such as those disclosed by Hancock, Dalton, Cone, and Tucker, which include a septum and a retained volume beneath the septum. (See Ensminger at col. 2, line 47- col. 3, line 9.)

For at least these reasons, Appellants submit that the Section 103 rejection of claims 113 and 114 should be reversed.

IX. Conclusion

For at least the reasons given above, the §§ 102(b) and 103(a) rejections applied to pending claims 60, 61, 63-68, 70-72, 74-79, 113, and 114 are improper. Accordingly, the Board of Patent Appeals and Interferences should reverse those rejections and permit allowance of all of the claims.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due which are not enclosed herewith, including any fees required for an

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extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

Dated: September 30, 2003

By: _____

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APPENDIX

Appealed Claims:

60. An access port device to be implanted in a patient's body, the access port device comprising:

a body portion comprising an upper body part, a lower body part attachable to the upper body part, and a self-sealing septum between the upper body part and the lower body part,

wherein the upper body part and the lower body part are formed of implantable, biocompatible material, and

wherein a reservoir is defined by the body portion;

an outlet configured to be in flow communication with the reservoir; and

an entry site located on the body portion, the entry site being disposed opposite the outlet and being configured to permit insertion of one of a guidewire and a stylet through the body portion and into the outlet,

wherein an outer surface of the septum forms a portion of an exterior surface of the device.

61. The device of claim 60, wherein the device further comprises an access site located on the upper body part.

63. The device of claim 60, wherein the entry site is located on the upper body part.

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64. The device of claim 60, wherein the reservoir is defined between the septum and the lower body part.

65. The device of claim 61, wherein the outlet extends away from the reservoir in a first direction, and wherein the access site extends away from the reservoir in a second direction substantially perpendicular to the first direction.

66. The device of claim 61, wherein the entry site extends away from the reservoir in a first direction, and wherein the access site extends away from the reservoir in a second direction substantially perpendicular to the first direction.

67. The device of claim 61, wherein the septum comprises a unitary, single-piece construction comprising a first septum portion and a second septum portion, the first septum portion providing access to the reservoir via the entry site and the second septum portion providing access to the reservoir via the access site.

68. An assembly comprising:

the device of claim 60; and

a catheter connected to the outlet.

70. An access port device to be implanted in a patient's body, the access port device comprising:

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a body portion comprising an upper body part, a lower body part attachable to the upper body part, and a self-sealing septum between the upper body part and the lower body part,

wherein the upper body part and the lower body part are formed of implantable, biocompatible material, and

wherein a reservoir is defined by the body portion;

an outlet configured to be in flow communication with the reservoir;

an entry site located on the body portion,

wherein the entry site is configured to permit access to the reservoir; and

an access site located on the body portion,

wherein the access site is configured to permit access to the reservoir, and

wherein an outer surface of the septum forms a portion of an exterior surface of the device.

71. The device of claim 70, wherein the access site is located on the upper body part.

72. The device of claim 70, wherein the entry site is disposed opposite the outlet.

74. The device of claim 70, wherein the entry site is located on the upper body part.

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75. The device of claim 70, wherein the reservoir is defined between the septum and the lower body part.

76. The device of claim 70, wherein the outlet extends away from the reservoir in a first direction, and wherein the access site extends away from the reservoir in a second direction substantially perpendicular to the first direction.

77. The device of claim 70, wherein the entry site extends away from the reservoir in a first direction, and wherein the access site extends away from the reservoir in a second direction substantially perpendicular to the first direction.

78. The device of claim 70, wherein the septum comprises a unitary, single-piece construction comprising a first septum portion and a second septum portion, the first septum portion providing access to the reservoir via the entry site and the second septum portion providing access to the reservoir via the access site.

79. An assembly comprising:

the device of claim 70; and

a catheter connected to the outlet.

113. A system comprising:

the access port device of claim 60; and

one of a guidewire and a stylet,

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wherein the entry site is configured to permit insertion of said one of a guidewire and a stylet through the body portion and into the outlet.

114. A system comprising:

the access port device of claim 70; and

one of a guidewire and a stylet,

wherein the entry site is configured to permit insertion of said one of a guidewire and a stylet through the body portion and into the outlet.

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